

**AWARD NUMBER:** W81XWH-14-2-0161

**TITLE:** Improving Diagnosis of Sepsis After Burn Injury Using a Portable Sepsis Alert System

**PRINCIPAL INVESTIGATOR:** Ravi S. Radhakrishnan, MD, MBA, FACS, FAAP

**RECIPIENT:** The University of Texas Medical Branch at Galveston  
Galveston, TX 77555

**REPORT DATE:** October 2016

**TYPE OF REPORT:** Annual

**PREPARED FOR:** U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

**DISTRIBUTION STATEMENT:** Approved for Public Release; Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. <b>PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.</b>					
1. REPORT DATE October 2016		2. REPORT TYPE Annual		3. DATES COVERED 30 Sep 2015 - 29 Sep 2016	
4. TITLE AND SUBTITLE  Improving Diagnosis of Sepsis After Burn Injury Using a Portable Sepsis Alert System				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-14-2-0161	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Ravi S. Radhakrishnan, MD, MBA, FACS, FAAP  Associate Professor, Department of Surgery The University of Texas Medical Branch at Galveston  E-Mail: rsradhak@utmb.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) The University of Texas Medical Branch at Galveston 301 University Boulevard Galveston, TX 77555-5302				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)  U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT  Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT <b>Background:</b> Sepsis is the leading cause of death after significant burn injury. Severely burned patients (TBSA >20%) have sepsis rates < 40%. Early initiation of antibiotics within 1 hour of recognition of sepsis is the only factor associated with better survival. Diagnosis of sepsis after burn injury is not amenable to standard sepsis criteria. To address this problem, the American Burn Association developed specific criteria to prompt sepsis workup. Despite these guidelines, these findings can be subtle leading to delays in recognition of sepsis. <b>Hypothesis:</b> Best practice guidelines using 'new vital signs' of heart rate variability, regional tissue oxygenation, and noninvasive cardiac output can diagnose burn sepsis earlier, reducing morbidity and mortality. <b>Rationale:</b> Heart Rate Variability (HRV), regional Tissue Oxygenation, and non-invasive Cardiac Output (CO), have shown promise in detecting sepsis in other patient populations. These modalities have not been evaluated for sepsis detection after burn injury. <b>Specific Aims/Study Design:</b> 1. Prospectively collect traditional and 'new vital signs' and compare the diagnostic accuracy, time to diagnosis, and prediction of outcome. 2. Develop a best practice guideline for the early diagnosis and treatment of sepsis in the burn patient, integrating current and new vital signs, and incorporating these into a bedside decision-support tool. 3. Design and conduct a prospective, multicenter, randomized study to test the efficacy of the newly developed bedside tool in detecting sepsis. <b>Relevance:</b> The use of 'new vital signs' will provide an improved assessment of burn sepsis, enabling earlier detection of sepsis. The results of the study may change the standard of burn care if it is found that 'new non-invasive vital signs' can detect sepsis earlier, leading to earlier initiation of antibiotics and improved morbidity and mortality.					
15. SUBJECT TERMS					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	18	19b. TELEPHONE NUMBER (include area code)

## TABLE OF CONTENTS

	<u>Page No.</u>
1. Introduction	4
2. Keywords	4
3. Accomplishments	4
4. Impact	6
5. Changes/Problems	7
6. Products	9
7. Participants & Other Collaborating Organizations	12
8. Special Reporting Requirements	14
9. Appendices	15
10. Attachment 1: Updated Other Support Information	16
11. Attachment 2: Quad Chart	18

1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

Despite multiple advances in critical care and resuscitation, sepsis is the leading cause of death in patients who sustain a significant burn injury. Our over-arching hypothesis is that best practice guideline using ‘new vital signs’ of heart rate variability, regional tissue oxygenation, and noninvasive cardiac output can be used to diagnose sepsis earlier, reducing morbidity and mortality after burn injury.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

Burn injury, sepsis, mortality, heart rate variability, regional tissue oxygenation, noninvasive cardiac output

3. **ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

**What were the major goals and objectives of the project?**

*List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.*

Task 1. Test the efficacy of “new noninvasive vital signs” of HRV, regional tissue oxygenation, and noninvasive cardiac output in detecting sepsis after burn injury. Proposed Timeline: Months 0-18. Patients to be enrolled: 20. Patients enrolled to date: 9. Adjusted completion date: Month 30.  
Task 2. Identify and use best conventional and “new” vital signs for early detection of burn sepsis to create a best practice guideline for identification of burn sepsis. Proposed Timeline: Months 6-18. Adjusted completion date: Month 30.  
Task 3. Create decision support tool using best practice guidelines. Proposed Timeline: Months 12-24. Adjusted completion date: Month 30.  
Task 4. Validate the efficacy of the bedside decision support tool to detect burn sepsis using multicenter, prospective study, bedside laptops, and patient sensors. Proposed Timeline: Months 30-48.

**What was accomplished under these goals?**

*For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.*

1. Post-doctoral Fellow (Min Zhu) hired. He has developed and tested the data collection system. Data now able to stream directly from bedside to secure servers in PI lab for analysis. Testing complete on system and ready to accept patient data. Nonin and Cardiotronic devices tested with Phillips bedside monitor. Current data collection system integrates and timestamps all data from various sources to allow accurate analysis.
2. IRB and HRPO approval obtained.
3. New Phillips data acquisition boards installed in every bedspace in burn unit. Will allow for data capture of multiple patients at lower cost than previously outlined.
4. Obtained device and sensors from Nonin. Obtained additional sensors from Cardiotronic.
5. RAID Server to store patient data with appropriate backup to prevent data loss has been fully tested and is currently collecting data.
6. Workstation to analyze data is currently working. Preliminary data analysis is being performed on data collected.
7. Since completion of Y1Q3, we have begun enrolling patients (for a total of 5 quarters). We have identified 12 patients who meet eligibility requirements for the study. We have enrolled and collected data on 9 of these patients (45% of proposed number). At this rate, we would have completed enrollment by month 39. In order to increase patient enrollment, we changed our study entry criteria from a minimum TBSA burn of 30% to 20%. This change will allow us to complete our patient enrollment by month 30.

**What opportunities for training and professional development has the project provided?**

*If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.*

Nothing to Report.

**How were the results disseminated to communities of interest?**

*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of*

*these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.*

Nothing to Report.

*Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.*

Continue to enroll eligible patients from the Blocker Burn Unit. We will continue to analyze the data obtained to create and modify our predictive algorithm for sepsis as more data becomes available. Begin patient enrollment at UTSW and UT Houston locations. Initially plan to order additional equipment for these facilities and obtain IRB approval at local sites.

- 4. IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

**What was the impact on the development of the principal discipline(s) of the project?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).*

Nothing to report.

**What was the impact on other disciplines?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.*

Nothing to report.

**What was the impact on technology transfer?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:*

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to report.

**What was the impact on society beyond science and technology?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:*

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to report.

- 5. CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:

**Changes in approach and reasons for change**

*Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.*

Our initial grant proposal included 30% TBSA as the minimum burn eligibility criteria for inclusion in the study. Over the past few months, we have had lower than expected patient enrollment. In order to improve our recruitment, we have made a change to our entry criteria, lowering the TBSA burn injury to 20%. This has improved our patient enrollment over the last quarter. This change has been approved by both our local IRB and the HRPO committees.

**Actual or anticipated problems or delays and actions or plans to resolve them**

*Describe problems or delays encountered during the reporting period and actions or plans to resolve them.*

As outlined above, patient enrollment at our institution has been slower than expected. In order to improve our ability to complete the initial patient enrollment, we have lowered our minimum TBSA burn to 20%. This has improved our patient eligibility for the study.

**Changes that had a significant impact on expenditures**

*Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.*

We were able to identify a more cost effective methodology to obtain patient data from the Philips monitor. This will allow us to shift the savings to obtain more patient sensors to enroll more patients.

**Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

*Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.*

**Significant changes in use or care of human subjects**

Change in enrollment criteria was approved by UTMB IRB committee on June 3, 2016.

**Significant changes in use or care of vertebrate animals.**

Not applicable.

**Significant changes in use of biohazards and/or select agents**

Not applicable.

**6. PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”

- **Publications, conference papers, and presentations**  
Report only the major publication(s) resulting from the work under this award.

**Journal publications.** *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title;*

*journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report.

**Books or other non-periodical, one-time publications.** *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: Author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report.

**Other publications, conference papers, and presentations.** *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (\*) if presentation produced a manuscript.*

Nothing to report.

- **Website(s) or other Internet site(s)**

*List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.*

Nothing to report.

- **Technologies or techniques**

*Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.*

Nothing to report.

- **Inventions, patent applications, and/or licenses**

*Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.*

Nothing to report.

- **Other Products**

*Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment, and/or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:*

- *data or databases;*
- *biospecimen collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Nothing to report.

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

### What individuals have worked on the project?

*Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate “no change.”*

#### Example:

*Name:* Mary Smith  
*Project Role:* Graduate Student  
*Researcher Identifier (e.g. ORCID ID):* 1234567  
*Nearest person month worked:* 5

*Contribution to Project:* Ms. Smith has performed work in the area of combined error-control and constrained coding.  
*Funding Support:* The Ford Foundation (Complete only if the funding support is provided from other than this award).

Name: Ravi Radhakrishnan  
Project Role: PI  
*No change*

Name: Min Zhu  
Project Role: Postdoctoral Fellow  
*No change*

Name: Omar Nunez-Lopez  
Project Role: Research Associate/Fellow  
*No change*

Name: Charles Mitchell, RN  
Project Role: Research Nurse  
Researcher Identifier (e.g. ORCID ID):  
Nearest person month worked: 1  
Contribution to Project: Mr. Mitchell will assure that research regulations are followed regarding clinical research activities, including IRB approval and SHC corporate research approval. He will maintain communication with the PI, reporting progress and any issues that arise. In addition, he will be responsible for pulling clinical data from patients' records, such as time of diagnosis of sepsis, initiation of antibiotics, and time when sepsis criteria are met as well as enrolling patients for the study. Finally, he helps with patient enrollment and data collection.

**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.*

Changes are reported in Attachment 1.

**What other organizations were involved as partners?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.*

*Provide the following information for each partnership:*

*Organization Name:*

*Location of Organization: (if foreign location list country)*

*Partner’s contribution to the project (identify one or more)*

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner’s facilities for project activities);*
- *Collaboration (e.g., partner’s staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner’s staff use each other’s facilities, work at each other’s site); and*
- *Other.*

Nothing to report.

## **8. SPECIAL REPORTING REQUIREMENTS**

**COLLABORATIVE AWARDS:** For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.

**QUAD CHARTS:** If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.

Attachment 2: Quad Chart

9. **APPENDICES:** Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

## CHANGES IN ACTIVE OTHER SUPPORT

### Radhakrishnan, Ravi S

#### Current

W81XWH-14-2-0161 (Radhakrishnan) 09/30/14-09/29/18 5%  
Dept of Defense \$329,216

"Improving Diagnosis of Sepsis After Burn Injury Using a Portable Sepsis Alert System"

Goal: To provide an improved assessment of burn sepsis, enabling earlier detection of sepsis leading to earlier initiation of antibiotics and improved morbidity and mortality.

Aims: 1) Prospectively collect traditional and 'new vital signs' and compare the diagnostic accuracy, time to diagnosis, and prediction of outcome; 2). Develop a best practice guideline for the early diagnosis and treatment of sepsis in the burn patient, integrating current and new vital signs, and incorporating these into a bedside decision-support tool; 3) Design and conduct a prospective, multicenter, randomized study to test the efficacy of the newly developed bedside tool in detecting sepsis.

Role: Principal Investigator

Contact: Eva Lai, Science Officer, eva.lai.civ@mail.mil; Tom Winter, Grants Specialist, thomas.s.winter2.civ@mail.mil

Overlap: This is the project for which the progress report is being submitted.

1 R01 GM112936-01 (Finnerty) 01/15/15-12/31/19 1%  
National Institutes of Health \$216,309

"Effects of Chronic Catecholamine Exposure on Post-burn Scarring"

Goal: Understanding the mechanisms underlying aberrant wound healing and scarring, and their reversal by propranolol, will lay the foundation to develop additional anti-scarring therapies for the severely burned.

Aims: Aim 1. Determine the effects of chronic catecholamine exposure and  $\beta$ -blockade on wound healing and hypertrophic scars. Aim 2. Quantitate the effects of  $\beta$ -blockade on scar composition. Aim 3. Determine the effects of  $\beta$ -blockade on  $\beta$ -AR expression, activity, and binding partners of dermal fibroblasts.

Role: Co-Investigator

Contact: Tseng, Hung H., 301-496-0810, tsengh@mail.nih.gov

Overlap: None.

### Kramer, George C

#### Current

W81XWH-14-2-0161 (Radhakrishnan) 09/30/14-09/29/18 3%  
Dept of Defense \$329,216

"Improving Diagnosis of Sepsis After Burn Injury Using a Portable Sepsis Alert System"

Goal: To provide an improved assessment of burn sepsis, enabling earlier detection of sepsis leading to earlier initiation of antibiotics and improved morbidity and mortality.

Aims: 1) Prospectively collect traditional and 'new vital signs' and compare the diagnostic accuracy, time to diagnosis, and prediction of outcome; 2). Develop a best practice guideline for the early diagnosis and treatment of sepsis in the burn patient, integrating current and new vital signs, and incorporating these into a bedside decision-support tool; 3) Design and conduct a prospective, multicenter, randomized study to test the efficacy of the newly developed bedside tool in detecting sepsis.

Role: Co-Investigator

Contact: Eva Lai, Science Officer, eva.lai.civ@mail.mil; Tom Winter, Grants Specialist, thomas.s.winter2.civ@mail.mil

Overlap: This is the project for which the progress report is being submitted.

HHSF223201450003 A (Kramer)	09/15/14-09/14/17	1.5%
Food and Drug Administration	\$72,551	
"Collection of Physiological Data Prior to Shock"		
Major Goal(s): This project is to provide physiological data, using a large animal model of hemodynamic shock.		
Role: Principal Investigator		
Sponsor Contact: U.S. Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993		
Overlap: None		

**\*\*\*Project or Effort Ended\*\*\***

N0001412C0556 (Kramer)	08/27/12-12/27/15	33%
W81XWH1210598 (Kinsky)	09/30/12-09/29/16	10%
3350 (Kramer)	08/27/14-08/26/16	1%

# Improving Diagnosis of Sepsis after Burn Injury Using a Portable Sepsis Alert System

Log Number: 13214029

Award Number: W81XWH-14-2-0161



**PI:** Ravi S. Radhakrishnan

**Org:** University of Texas Medical Branch

**Award Amount:** \$1,247,316

## Study/Product Aim(s)

Task 1. Test the efficacy of “new noninvasive vital signs” of HRV, regional tissue oxygenation, and noninvasive cardiac output in detecting sepsis after burn injury. Adjusted completion date: Month 30.

Task 2. Identify and use best conventional and “new” vital signs for early detection of burn sepsis to create a best practice guideline for identification of burn sepsis. Adjusted completion date: Month 30.

Task 3. Create decision support tool using best practice guidelines. Adjusted completion date: Month 30.

Task 4. Validate the efficacy of the bedside decision support tool to detect burn sepsis using multicenter, prospective study, bedside laptops, and patient sensors. Proposed Timeline: Months 30-48.

## Approach

Continue patient enrollment. Have changed entry criteria to allow more patients to be eligible for study. Currently working to examine possible predictive variables for decision support tool creation in burn sepsis.

Based on preliminary analysis of our patients, we have identified the following variables as significantly different between septic burn patients and burn patients.

Mean Heart Rate, Mean RR interval, pNN, and SD1/SD2.

Activities	FY	15	16	17	18
Collect Preliminary Data and Create Multivariable Algorithm					
Create Multivariable algorithm and portable decision support tool					
Conduct Prospective Multicenter Study					
Estimated Budget (\$K)		\$307K	\$267K	\$395K	\$332K

## Goals/Milestones

### FY15 Goal –

- ☒ Complete IRB approval
- ☒ Obtain HRPO approval
- ☒ Obtain Monitors, Data analysis computers
- ☒ Begin Patient Enrollment

### FY16-17 Goals

- ☐ Develop Multivariable Algorithm
- ☐ Create Portable Decision Support Tool
- ☐ Begin patient enrollment at UT Houston and UTSW
- ☐ Obtain IRB approval at other sites

### Comments/Challenges/Issues/Concerns

- Patient enrollment behind projected figures. Based on historic data and wider entry criteria, patient enrollment should improve.

### Budget Expenditure to Date

Projected Expenditure: \$574,000.00

Actual Expenditure: \$376,957.64

**Updated:** October 28, 2016.